NHS West Yorkshire
Integrated Care Board

West Yorkshire Integrated Care Board (WY ICB)					
Policy	**Sacral nerve stimulation for chronic constipation**			**ICB Ref**	Planned care
First Issue Date	To be confirmed	**Current version:**	1	**Last reviewed:**	May 2022
Review date	To be confirmed	**Contact**	West Yorkshire Health and Care Partnership (WY HCP) wyhcp.plannedcare@nhs.net		
Clinical Reviewer	WY HCP	**Approved by**	WY ICB		

Policy exclusions

This policy relates to the use of Sacral Nerve Stimulation (SNS) for patients with slow transit constipation.

All other uses for SNS are excluded and will not be covered under this policy

Policy inclusion criteria

The ICB considers funding SNS therapy for slow transit constipation for those patients who:

- Have a minimum 1 year history of slow transit chronic constipation;
- Clinical judgement is that bowel surgery would be required within 2 years;
- Have symptoms refractory to conservative treatment including diet, exercise, lifestyle changes and bowel retraining programmes;
- Have limited success using laxative therapies;
- Have undergone a 2 week PNE trial phase with either a 50% improvement in voiding frequency based on a stool diary or a 50% improvement in constipation quality of life score.

NB this policy is based on best possible assessment of evidence at the time of last review (2019) and will need to be reviewed and revisited once the outcomes of the Dutch study are known.

An enhancement for people of West Yorkshire living in Bradford District and Craven, Calderdale, Kirklees and Wakefield. This is policy is currently only in place in the Leeds areas. It is being widened across all areas in West Yorkshire.

Summary of evidence / Rationale	Sacral Nerve Stimulation for Chronic Constipation, Policy Recommendation July 2019 – See Appendix 1
Reference	1. Sacral nerve stimulation for faecal incontinence: NICE guidance [IPG99] Published: 23 February 2008

https://www.nice.org.uk/guidance/ipg99

2. Sacral nerve stimulation for faecal incontinence: NHS England Published June 2013 https://www.england.nhs.uk/wp-content/uploads/2018/07/Sacral-nerve-stimulation-for-faecal-incontinence-Adult.pdf
3. **Heemskerk S, Rotteveel A and Benninga M** Sacral neuromodulation versus personalized conservative treatment in patients with idiopathic slow-transit constipation: study protocol of the No.2-trial, a multicenter open-label randomized controlled trial and cost-effectiveness analysis [Journal]. - [s.l.] : International journal of colorectal disease, Apr 2018. - 4 : Vol. 33. - pp. 493-501.
4. **Maslekar S and Jayne D G** The Management of Constipation [Book Section] // Contemporary Coloproctology / book auth. Brown S [et al.]. - London : Springer, 2012.
5. **NICE** Clinical Knowledge Summary: Constipation [Online] // National Institute for Health and Care Excellence. - 2017. - https://cks.nice.org.uk/constipation#!scenario.
6. **Roque Maria Vazquez and Bouras Ernest P** Epidemiology and managemetn of chronic consitpation in elderly patients [Journal]. - [s.l.] : Clin Interv Aging, 2015. - Vol. 10.
7. **Thaha MA [et al.]** Sacral nerve stimulation for faecal incontinence and constipation in adults (Review) [Journal] // Cochrane Database of Systematic Reviews. - 2015. - 8.
8. **Wilt van der, Groenewoud HHM and Benninga MA** Cost-effectiveness of sacral neuromodulation for chronic refractory constipation in children and adolescents: a Markov model analysis. [Journal]. - [s.l.] : Colorectal Disease, 2017. - 19 : Vol. November.

Appendix 1

Briefing Title: Sacral Nerve Stimulation for Chronic Constipation, Policy Recommendation July 2019

1.0 Purpose

The purpose of this briefing note is to provide a background on chronic constipation, review the indications and effectiveness of Sacral Nerve Stimulation (SNS) in treating chronic constipation, and to make a funding policy recommendation to Leeds Clinical Commissioning Group for the appropriate use of SNS.

2.0 Background

2.1 Chronic Constipation (CC) can be defined as less than 3 bowel movements per week with associated symptoms lasting at least 3 months. It affects around 20% of children and adults, with estimates varying from 2% to 27% and is more common in women and the elderly (Roque, et al., 2015).

2.2 Primary causes of constipation are: idiopathic slow transit, irritable bowel syndrome and obstructive defecation syndrome (Maslekar, et al., 2012).

2.3 The majority of CC cases are left untreated. Conservative treatment is successful in 85% of patients and includes dietary changes, physical activity, and increased fluids. A small minority of patients with more disabling symptoms will be referred to secondary care.

2.4 Secondary care pathways are stepwise, starting with conservative treatments as above in addition to a series of laxatives and moving on to nurse-led bowel retraining programs including biofeedback. These treatments are successful in about 50% of patients. The remaining patients may then be offered surgical interventions where there is slow transit constipation and pelvic floor dysfunction has been ruled out as a primary cause (NICE, 2017).

2.5 Surgical interventions considered, such as partial colectomy with ileorectal anastomosis (removing the colon and connecting the ileum to the rectum) or an ileostomy to form a stoma, are generally irreversible.

2.6 SNS is considered in those patients where conservative, pharmacological and bowel retraining interventions have failed.

2.7 In SNS therapy, low-voltage electrical stimulation is applied to the sacral spinal nerves either directly or indirectly with the intention to recruit pelvic organ function. It is used for bladder and faecal function for both incontinence and constipation/retention. The mechanism for these seemingly contradictory uses is not well understood (Thaha, et al., 2015).

2.8 NICE supports the use of SNS for urinary incontinence (IPG64), idiopathic chronic non-obstructive urinary retention (IPG536), and faecal incontinence (IPG99). As such, these procedures are commissioned routinely by NHS England specialised commissioning. NICE does not have guidance on the use of SNS for chronic constipation and it is therefore only funded where CCGs have agreed to do so locally.

2.9 For all applications of SNS, patients undergo a trial phase on stimulation via a peripherally applied stimulator (PNE). The more permanent SNS device is only implanted for patients whose symptoms improve during trial to a specified threshold. The threshold is usually set at 50% improvement over a 2-3 week period.

2.10 SNS costs Leeds CCG commissioners £10,477 per implant. This includes £245 for the trial PNE and £7,050 for the SNS system, both as pass through costs. There is a £716 tariff for the PNE procedure and £2,466 tariff for the SNS procedure. The most common SNS device requires replacing every 5 years, though a new system is being introduced that is rechargeable and lasts 9 years.

3.0 Methodology

3.1 To assess the clinical and cost effectiveness of SNS for chronic constipation I used three methods:

3.1.1 A literature search for all relevant studies. Because there is a comprehensive Cochrane Systematic Review on this topic, I looked for literature published after the review's search parameters (2015 on).

3.1.2 Consultation with a consultant in Leeds who has previously requested funding SNS for constipation via an IFR.

3.1.3 An audit of all constipation related SNS procedures in the past 4 years amongst LTHT patients.

4.0 Findings

4.1 The Cochrane Review on "Sacral nerve stimulation for faecal incontinence and constipation in adults" is a robust systematic review of relevant randomised and quasi-randomised trials up to 2015. Strict selection criteria rule out studies with poor methodological quality.

4.2 The Review only found two adequate studies looking at constipation, with a total of 61 participants. These studies showed that SNS did not improve symptoms compared to sham treatments (the review did confirm that SNS for faecal incontinence was effective). The constipation studies did not include economic analyses.

4.3 Unfortunately these studies randomised all eligible chronic constipation patients to either receive SNS or a sham treatment regardless of their experience in the trial PNE phase. The larger study did find that PNE is a poor predictor of positive outcomes from SNS (50% PPV) and a good predictor of negative outcomes (78% NPV).

4.4 On request, the Leeds Teaching Hospital library service ran a comprehensive search for studies from 2015 on. Of 47 hits, six were relevant.

4.5 Three of four uncontrolled case studies (single centre, non-randomised) found SNS effective. These were analyses of cases with no control group, but showing that symptoms significantly improved for those patients receiving SNS after a successful PNE trial.

4.6 A 2017 study assessing the cost effectiveness of SNS in children aged 10-18 found a mean cost effectiveness ratio of £11,000 per QALY (Wilt, et al., 2017). This falls below the general NICE threshold for cost-effectiveness of £25,000 per QALY. The study compared the costs and quality of life for those with SNS implants and those who either continued conservative treatment or underwent surgery. While positive, this is just one study of 30 female patients and should not be used for any cost modelling.

4.7 The search revealed a study protocol (Heemskerk, et al., 2018) funded by the Dutch Ministry of Health who are conducting a large randomised multi-centre trial on the clinical and cost-effectiveness of SNS in slow transit constipation. The results are due to be published in 2021.

4.8 I met with Mr Sushill Maslekar, a colorectal surgeon at LTFT, in May 2019. Mr Maslekar has submitted six out of seven SNS IFR requests from LTFT in the last three years. We discussed the local protocol, pathways and evidence base used to consider SNS as a treatment options.

4.9 LTFT appears to follow the standard PNE trial phase pathway seen elsewhere, looking for 50% improvement on baseline over two weeks before submitting an IFR for SNS implantation. SNS is considered only in those patients failing conservative and drug therapy and where the next consideration is surgical.

4.10 Mr Maslekar highlighted the cost and quality of life implications for attempting SNS therapy over major bowel surgery. He suggested the positive predictive value of PNE for SNS was very high locally and that the cost-benefits calculus would likely support its use considering the alternatives.

4.11 On request, colorectal staff at LTHT performed an audit of patients over the last 11 years who were considered for SNS as treatment for chronic constipation. The audit revealed 50 cases, all of whom underwent a PNE trial phase.

4.11.1 There were 22 cases where SNS was implanted in line with the 50% improvement threshold for PNE testing. The majority (88%) are female and the average age is around 40.

4.11.2 Five of these 22 cases (23%) have subsequently had the implant removed or turned off for being ineffective. A stoma is now present in one of these cases.

4.11.3 23 cases (38%) failed the PNE trial and did not receive SNS. These will not have progressed to the IFR panel.

4.11.4 Four cases have met SNS criteria, but are waiting for the procedure.

4.11.5 SNS was implanted in one case from 2014 that did not meet the 50% improvement threshold during PNE testing.

5.0 Conclusions

5.1 SNS therapy is proven highly effective for faecal incontinence, urinary incontinence and urinary retention.

5.2 There is limited high-quality evidence showing SNS is effective or ineffective for slow-transit chronic constipation. The available randomised trials are poorly powered and do not mimic the standard practice of trialling peripheral stimulation prior to SNS implantation.

5.3 One economic evaluation shows SNS as cost effective. The alternative to SNS treatment is usually surgery with variable outcomes and long term side effects.

5.4 The Dutch government is looking to make a funding decision on SNS for constipation and has sponsored a large multi-centre randomised trial due to be published in 2021.

5.5 An audit of cases in Leeds shows the majority of patients receiving SNS are meeting established criteria for improvement during a trial PNE phase. Nearly a quarter of these patients subsequently have the device switched off or removed after experiencing limited clinical effect. Three quarters of these patients, or about two a year since 2008 have potentially avoided bowel surgery for the duration of their treatment.

6.0 Recommendations

6.1 Leeds CCG considers funding SNS therapy for slow transit constipation for those patients who[1]:

6.1.1 Have a minimum 1 year history of slow transit chronic constipation;

6.1.2 Clinical judgement is that bowel surgery would be required within 2 years;

6.1.3 Have symptoms refractory to conservative treatment including diet, exercise, lifestyle changes and bowel retraining programmes;

6.1.4 Have limited success using laxative therapies;

6.1.5 Have undergone a 2 week PNE trial phase with either a 50% improvement in voiding frequency based on a stool diary or a 50% improvement in constipation quality of life score.

6.2 The funding policy is reviewed in 2022 following the publication of the Dutch randomised control trial.

Questions about this briefing note?

For more information or to review any issues raised in this briefing note please contact:

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References

Heemskerk S, Rotteveel A and Benninga M Sacral neuromodulation versus personalized conservative treatment in patients with idiopathic slow-transit constipation: study protocol of the No.2-trial, a multicenter open-label randomized controlled trial and cost-effectiveness analysis [Journal]. - [s.l.] : International journal of colorectal disease, Apr 2018. - 4 : Vol. 33. - pp. 493-501.

Maslekar S and Jayne D G The Management of Constipation [Book Section] // Contemporary Coloproctology / book auth. Brown S [et al.]. - London : Springer, 2012.

[1] These criteria are based on those used when SNS is prescribed for faecal incontinence and bladder control.

NICE Clinical Knowledge Summary: Constipation [Online] // National Institute for Health and Care Excellence. - 2017. - https://cks.nice.org.uk/constipation#!scenario.
Roque Maria Vazquez and Bouras Ernest P Epidemiology and managemetn of chronic consitpation in elderly patients [Journal]. - [s.l.] : Clin Interv Aging, 2015. - Vol. 10.
Thaha MA [et al.] Sacral nerve stimulation for faecal incontinence and constipation in adults (Review) [Journal] // Cochrane Database of Systematic Reviews. - 2015. - 8.
Wilt van der, Groenewoud HHM and Benninga MA Cost-effectiveness of sacral neuromodulation for chronic refractory constipation in children and adolescents: a Markov model analysis. [Journal]. - [s.l.] : Colorectal Disease, 2017. - 19 : Vol. November.